UNITED STATES DISTRICT COURT
DISTRICT OF MINNESOTA

IN RE: NATIONAL HOCKEY LEAGUE PLAYERS' CONCUSSION INJURY LITIGATION	)	MDL No. 14-2551 (SRN/JSM)
This Document Relates to: ALL ACTIONS	)	

DEFENDANT NATIONAL HOCKEY LEAGUE'S SUPPLEMENTAL MEMORANDUM IN SUPPORT OF ITS MOTION TO COMPEL PRODUCTION OF DOCUMENTS FROM THE BOSTON UNIVERSITY CTE CENTER

The National Hockey League ("NHL") moved to enforce the subpoena duces tecum served on the Boston University CTE Center ("BU CTE Center" or the "Center"). This Court heard argument on the motion at its February 17, 2017 status conference. The NHL now files this supplemental memorandum for two purposes. First, during oral argument, the Court requested that the NHL identify instances in which peer-reviewed articles have been called into question following production of underlying data. (Dkt. No. 712, at 64-65.) In this brief, the NHL has collected cases in which (1) a court excluded expert testimony after a peer-reviewed article on which it was based was undermined by discovery regarding the article; and (2) a court has ordered production of data underlying a peer-reviewed article. Second, the NHL wishes to respond to the March 2, 2017 Supplemental Affidavit of Ann C. McKee, M.D. (Dkt. No. 717).

BACKGROUND

By its motion, the NHL seeks certain data underlying the BU CTE Center's published research articles in order, *inter alia*, to ensure that the observations set forth

therein align with those data and to evaluate the validity of Dr. Robert Cantu's reliance on those articles in his role as Plaintiffs' expert. The fact that those articles have been peer-reviewed should not bar the NHL's request or otherwise immunize the BU CTE Center from appropriate discovery. As acknowledged by Dr. Cantu in his recent deposition, "Peer-reviewed doesn't make [an article] right. Peer-reviewed just means it's been peer-reviewed." (February 22, 2017 Deposition of Robert Cantu, 79:12-13.)

This very concern is recognized in the Federal Judicial Center's *Manual on Scientific Evidence*, which states that it is a "Myth" that "[t]he institution of peer review assures that all published papers are sound and dependable." Federal Judicial Center, *Reference Manual on Scientific Evidence* (3d ed. 2011), at 48. Instead, the Manual identifies as a "Fact" that "[p]eer review generally will catch something that is completely out of step with majority thinking at the time, but. . . is not very good at dealing with truly novel ideas. Peer review mostly assures that all papers follow the current paradigm. . . . It certainly does not ensure that the work has been fully vetted in terms of the data analysis and the proper application of research methods." *Id*. at 48. These concerns are also echoed by legal scholars. *See, e.g.*. Frank C. Woodside, III & Michael J. Gray, *Researchers' Privilege: Full Disclosure*, 32 W. Mich. U. Thomas M. Cooley L. Rev. 1, 16 (2015) ("[P]eer reviewers do not have the time or ability to replicate each researcher's study to check its validity.").

ANALYSIS

I. COURTS HAVE REGULARLY EXCLUDED PEER-REVIEWED ARTICLES BASED ON ERRORS FOUND DURING DISCOVERY.

In some cases, courts have ordered third parties to produce the data underlying peer-reviewed articles relied upon by expert witnesses. In other cases, no such order has been necessary because the authors of peer-reviewed articles are often retained to provide expert testimony based on their own work and produce the underlying data without objection.[1] Regardless of the production process, the revelation of those data has resulted in challenges to scientific studies that have heavily influenced outcomes of multiple MDL/mass tort proceedings.

For example, as noted during oral argument (Dkt. No. 712, at 63), the court allowed discovery of peer-reviewed scientific data in the Viagra MDL pending in this

[1] Plaintiffs' lead science expert, Dr. Robert Cantu, in large part bases his expert opinions on the work he has done with the BU CTE Center, the articles that he has co-authored with personnel from the Center, and the testing the Center has performed on retired NHL hockey players. (*See, e.g.*, Cantu Decl., Dkt. 646 ¶¶ 8, 57, 58, 60, 95, 99, 101, 102, 103, 104, 105, 107.) Yet, apparently in an effort to shield against discovery, the BU CTE Center (with support from plaintiffs) has sought to minimize the role Dr. Cantu plays in the research it conducts. *See, e.g.*, Tr., Dkt. No. 712, at 30 ("Dr. Cantu has an affiliation with Boston University, but that does not make Boston University a party or a participant in this litigation."); *id.* at 27 ("Dr. Cantu has no more access to [the data underlying the published information] than any of us in this courtroom do."). But outside this litigation, the BU CTE Center has publicly proclaimed Dr. Cantu's substantial, integral involvement in the research it conducts and publishes. *See, e.g.*, Connolly Decl. Exhibit A (photograph showing Dr. Cantu with Dr. McKee and Dr. Stern examining brain samples). For example, Dr. McKee identifies Dr. Cantu as a co-author of seven of her peer reviewed articles and six of her case reports (*see* McKee CV, Dkt 682-1), and Dr. Stern identifies Dr. Cantu as a co-author of 19 of his peer reviewed articles, two of his invited papers, and two of his text book chapters. (*See* Stern CV, Dkt. 683-1.) Likewise, Dr. Cantu identifies himself as a "Co-Founder" of the BU CTE Center. (Cantu Dec. Dkt. 646 ¶ 8.)

district. *See generally In re Viagra Prod. Liab. Litig.*, 658 F. Supp. 2d 936, 939-40 (D. Minn. 2009). In that case, plaintiffs proffered an expert, Dr. McGwin, who had published a peer-reviewed study on alleged side effects of Viagra while at the University of Alabama at Birmingham ("UAB"). *Id*.

The Court initially denied defendant's motion to exclude McGwin, "largely because 'the McGwin. . . stud[y was] peer-reviewed, published, contain[ed] known rates of error, and result[ed] from generally accepted epidemiologic research.'" *Id.* at 940. However, when defendant sought additional discovery into McGwin's article and its underlying data, the court allowed it. *In re Viagra Prod. Liab. Litig.*, 572 F. Supp. 2d 1071, 1082 (D. Minn. 2008). Although the briefing was filed under seal, it appears the defendants moved for production of data underlying McGwin's peer-reviewed articles, controlled by the University of Alabama Birmingham (UAB), *see In re Viagra Prod. Liab. Litig.*, No. 0:06-md-01724-PAM (D. Minn. 2008), Dkt. No. 535, while plaintiffs and third-parties McGwin and UAB resisted this motion. *In re Viagra Prod. Liab. Litig.*, No. 0:06-md-01724-PAM (D. Minn. 2009) Dkt. No. 538, 540. (Not supplied because filed under seal).

Ultimately, the Court ordered Dr. McGwin and third-party UAB to produce the raw data underlying McGwin's published study. *In re Viagra Prod. Liab. Litig.*, 658 F. Supp. 2d at 940; Order, *In re Viagra Prod. Liab. Litig.*, No. 0:08-cv-01440-PAM (D. Minn. 2009), Dkt. No. 6 (attached hereto as Connolly Decl. Exhibit B). In reviewing the data disclosed pursuant to this discovery order, the defendant discovered that McGwin had miscoded whether certain study subjects had taken Viagra prior to suffering the

alleged side effects. *In re Viagra Prod. Liab. Litig.*, 658 F. Supp. 2d at 942. The defendant also found that "the statistical methods used to produce the numbers in the McGwin Study as published were not the statistical methods that the McGwin Study said were used." *Id.* at 944. As a result of these findings, Dr. McGwin's peer-reviewed study was excluded. *Id.* at 950.

As discussed during oral argument, the *Viagra* case is not the lone example of a court excluding an expert for reliance on a flawed peer-reviewed article. Famously, Dr. Andrew Wakefield published an article in The Lancet finding that the measles-mumps-rubella (MMR) vaccine was associated with autism. A.J. Wakefield, et al., "Ileal-lymphoid-nodular hyperplasia, non-specific colitis, and pervasive developmental disorder in children," 351 Lancet 637 (1998). This study, which Wakefield published thanks to funding from litigation counsel, was highly controversial. *See* Brian Deer, *MMR Doctor Given Legal Aid Thousands*, THE SUNDAY TIMES, Dec. 31, 2006. Ultimately, The Lancet retracted the article due, in part, to Wakefield manipulating his raw data to tell a different story in his article. Editors of the Lancet, "Retraction—Ileal-lymphoidnodular hyperplasia, non-specific colitis, and pervasive developmental disorder in children," 375 Lancet 445 (2010). However, prior to that retraction, the lack of connection between the article's conclusions and its underlying data led the U.S. Court of Federal Claims to disregard the testimony of multiple experts that relied on the peer-reviewed article. *Cedillo v. Secretary of Health and Human Services*, 2009 WL 331968, at *79, 109-111 (Fed. Cl. Feb. 12, 2009).

Similarly, a New Jersey court excluded an expert relying on his own peer-reviewed article for several flaws made evident by the revelation of the study's raw data – or lack thereof. *Palazzolo v. Hoffman La Roche, Inc.*, 2010 WL 363834 (N.J. App. Div. 2010). In that case, the expert had published a peer-reviewed article associating Accutane with depression. *Id.* at *1. However, after defendants had a chance to review the study's underlying data, the expert "was repeatedly confronted with problems in the. . . study, including missing data, inaccurate data, and deviations from the methodology he claimed to have followed." The trial court therefore excluded the study, and an appellate court upheld the ruling. *Id.* at *4-5 ("An expert's scientific peers cannot fairly judge the expert's written work, including whether it is worthy of publication, if his article does not accurately represent either the underlying data or what the author did to produce his results.").

Moreover, 20 years ago, in the *Silicone Gel Breast Implant Prod. Liab. Litig.* MDL proceeding, the court allowed defendants to challenge underlying peer-reviewed articles on which plaintiffs' experts relied. The *Silicone Gel Breast Implant* litigation involved allegations that silicone gel breast implants caused a wide variety of autoimmune or autoimmune-like diseases. During discovery, the court permitted defendants to discover whether "existing studies, research, and reported observations provide a reliable and reasonable scientific basis for one to conclude that silicone gel breast implants cause of exacerbate any of the conditions" allegedly associated with SBIs. *In re Silicone Gel Breast Implant Prod. Liab. Litig.* (MDL 926), No. CV 92-P-10000-S, 1996 WL 34401766, at *1 (N.D. Ala. Oct. 31, 1996). After reviewing all of the

studies and the underlying data, the scientific panel the court appointed totally rejected the peer-reviewed studies that were the basis of plaintiffs' claims. *See* B.A. Diamond et al., *Silicone Breast Implants in Relation to Connective Tissue Diseases and Immunologic Dysfunction* (1998), http://www.fjc.gov/BREIMLIT/SCIENCE/summary.htm (last visited Mar. 7, 2017).

These holdings demonstrate why publishers of peer-reviewed articles should not be immune from discovery and why a party should have an opportunity to scrutinize the data underlying studies relied upon by an opponent's experts. Well-intentioned researchers may make mistakes, and the NHL deserves the opportunity to explore that possibility here.

II. IN SIMILAR CASES, COURTS HAVE ORDERED PRODUCTION OF THE RAW DATA UNDERLYING PEER-REVIEWED ARTICLES

Not only have MDL courts excluded experts on the basis of problematic data, but these courts have commonly allowed discovery of data underlying peer-reviewed studies. Often, courts have ordered third-parties to produce the data underlying their peer-reviewed studies with little need for elaboration beyond providing protections for the confidentiality of study subjects. *See, e.g.*,

- Order re: WHI Extension Study Data, *In re Prempro Prods. Liab. Litig.*, No. 4:03-CV-1507-WRW (E.D. Ark. July 13, 2009), Dkt. No. 2106 (attached hereto as Connolly Decl. Exhibit C);
- Order re: Motion to Quash Subpoenas re Yale Study's Hospital Records, *In re: Phenylpropanolamine (PPA) Prods. Liab. Litig.*, MDL No. 1407 (W.D. Wash. Aug. 19, 2002), Dkt. No. 878 (attached to prior filing, Dkt. No. 674-1);
- *Kellington v.* Bayer *Healthcare Pharm., Inc.*, No. 5:14-cv-2, 2016 WL 5349801, at *2 (W.D. Va. Sept. 23, 2016) ("[T]here is no blanket prohibition

> set forth in the discovery rules against discovery directed at third-party academics. . . .").

Other courts have recognized that although the peer review process is valuable, it cannot immunize the underlying data from appropriate discovery. For example, in *In re NCAA Student-Athlete Name & Likeness Licensing Litig.*, No. 4:12-MC-00508 JAR, 2012 WL 4856968 (E.D. Mo. Oct. 12, 2012), the court recognized that "peer review is a critical step in finalizing and adding credibility to a research study." 2012 WL 4856968, at *3. Nonetheless, recognizing that peer review is no substitute for independent review of a researcher's data, the court granted the movant access to a third-party author's dataset upon completion of the peer review process. *Id.* at 4.

The courts in both the *NCAA Student-Athlete* and *PPA* cases relied on the reasoning of *Deitchman v. E.R. Squibb & Sons, Inc.*, 740 F.2d 556, 558 (7th Cir. 1984), to support the production of data. As noted at oral argument (Tr., Dkt. No. 712, at 13-14), *Deitchman* is the most analogous case to the present dispute, and although that case was not part of an MDL proceeding, its reasoning fully applies to the issue at hand. In its opening brief (Dkt. 669, at 15-16), the NHL explained that *Deitchman* stands for the proposition that third-party researchers may not protect their raw data on the basis of any privilege. Moreover, the Seventh Circuit ordered production of the data underlying multiple peer-reviewed articles even when the moving party made "absolutely no allegation in the record of any impropriety" in the researcher's work, *Deitchman*, 740 F.2d at 562, and even though the third-party researcher faced "loss of confidential information" and "financial and temporal costs." *Id.* at 564. The Seventh Circuit found

movants desire to "critically scrutinize" and "effectively and efficiently cross-examine" plaintiffs' experts was sufficient grounds for production. *Id.* at 562. As such, *Deitchman* stands for the proposition that for a movant "to prepare properly a defense on the causation issue, access to the. . . data to analyze its accuracy and methodology is absolutely essential." *Id.* at 563.

The *Deitchman* opinion has been followed in the District of Minnesota in opinions ordering the disclosure of data that was not publicly available. *Kramer v. Boeing Co.*, 126 F.R.D. 690, 695–96 (D. Minn. 1989) ("Ordinarily, information which is of a confidential or proprietary nature is not, for that reason alone, outside the parameters of civil discovery."); *Simon v. G.D. Searle & Co.*, 119 F.R.D. 680, 682 (D. Minn. 1987) ("Balancing Searle's stated interests against plaintiffs' substantial need for data from the Study favors discovery.").

Similarly, *Wright v. Jeep Corp.*, 547 F. Supp. 871 (E.D. Mich. 1982), like *Deitchman*, is a non-MDL opinion that provides persuasive support for the principle that a party's need to analyze an adverse article's raw data outweighs any burden to a third-party researcher. In *Wright*, movants sought to uncover the raw data for a study on vehicle performance in car crashes conducted by a professor who had not been retained as an expert. Although the professor was not a retained expert, the court found "a high probability that the result of [the professor's] research will be used at trial by plaintiff. . . ." *Wright*, 547 F. Supp. at 874. The court pointed to no facts indicating an expectation that the professor's research would be flawed. Rather, the court recognized the principle of discovery that "it is necessary that *all* relevant evidence be made

available for the resolution of disputes. . .” was more important than any burden placed on the professor. In fact, the court recognized the burden it placed on the professor, stating:

> A researcher who spends a great deal of time and effort in uncovering information that becomes important *in many lawsuits* is subject to a heavy burden. The solution is not to cover-up the information or its data base because disclosure is too burdensome but to use the tools available to lessen the burden and to permit the information to become available.

Wright, 547 F. Supp. at 877 (emphasis added).

The foregoing cases make clear that an order for production of third-party raw data is well-supported by case law.

III. DR. MCKEE’S AFFIDAVIT FAILS TO ADDRESS THE COURT’S QUESTIONS OR SUBSTANTIATE THE BU CTE CENTER’S OPPOSITION TO DISCOVERY

Following oral argument, the Center filed a supplemental affidavit of Dr. Ann McKee (Dkt. 717) to respond to some questions asked by the Court during the hearing.

The Court specifically asked BU for information about which of the Center’s materials had been reviewed during the peer review process. (Dkt. 712, at 54, 57-58.) In her response, Dr. McKee provided the Court with another overview of the peer review process and more general information about certain data BU has made public. But her affidavit offers no confirmation that the brain tissue slides the NHL seeks were made available to or examined by peer reviewers of the BU CTE Center’s articles. (Dkt. No. 717, ¶ 9-15.) Dr. McKee states vaguely that “photomicrographs and photographs” of brain tissue slides are provided to reviewers. *Id.* ¶ 10. However, Dr. McKee does not indicate whether all slides were provided to those reviewers or whether those slides were

actually reviewed. Thus, the record still contains no evidence that the brain tissue slides the NHL seeks were actually scrutinized during any peer-review process.

The NHL also notes that BU originally opposed the NHL's request by arguing that the NHL's request would bring its work to a "grinding halt" due the time and effort it would take to produce these slides. (BU Mem.., Dkt. No. 680, at 27.) In her original affidavit, Dr. McKee discussed at length the burden of providing the NHL with copies of the fragile glass brain tissue slides (*see, e.g.*, McKee Dec., Dkt. No. 682, ¶¶ 19-23, 28), making no mention of the fact that the CTE Center had already made digitized copies of those slides for safekeeping and that the NHL had offered to accept copies of those digitized versions. (NHL Reply, Dkt. No. 694, at 12, n.17.) Although voluminous, those digitized slides are easily copied. Thus, the new McKee affidavit confirms that much of the burden argument in her original affidavit is irrelevant.

Accordingly, the Court should dismiss BU's arguments and grant the NHL's motion to compel.

CONCLUSION

Based on the case law set forth above, the NHL respectfully requests that the Court grant its motion and compel the BU CTE Center to produce relevant materials requested in the subpoena.

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Respectfully submitted,

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